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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/508,339

10/25/2004

Koji Teshima

2004-1514A

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09/12/2008

WENDEROTH, LIND & PONACK, L.L.P.

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WASHINGTON, DC 20006-1021

EXAMINER

O'DELL, DAVID K

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

09/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/508,339	Applicant(s) TESHIMA ET AL.	
	Examiner David K. O'Dell	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-13 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-13, 28 is/are allowed.
- 6) ☒ Claim(s) 21-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 10-13, 21-28 are pending in the current application.
2. This application is a national stage of PCT/JP03/03925 filed March 28, 2003, and claims priority to Japanese Application 200293398 filed March 29, 2002.

Response to Arguments

3. Applicant's arguments filed on June 18, 2008 have been fully considered but they are not fully persuasive. Rejections of cancelled claims are withdrawn. The rejection of the claims 10-13, 28 are withdrawn based on the claim amendments, since R1 is no longer H and restricted to alkyl amido, the basis of the examiner's rejection is overcome. In addition the applicant has pointed to comparative data for Ro-65-6570 vs. the instantly claimed compound. The prior art is silent as to why one would choose these two modifications (acenaphthalene and alkylamido) since no data is provided for any compounds with alkylamido groups on the imidazolone. It is unclear why one would pick the particular groups that applicant has selected.

The rejection of claims 21-27 under 35 U.S.C. 112 1st paragraph is maintained for the reasons of record. Applicants' representative argues that the specification gives sufficient guidance to the skilled artisan to treat "sleep disorders" with the compounds of the instant case, pointing to examples 3-5, which use a compound in tests for sleep disorders. Applicant's arguments have been fully considered but have not been found to be persuasive. The claims require treatment of circadian rhythm sleep disorders. Dawson et. al. states that:

"Inferring a chronobiotic effect for a drug on the basis of an action on complex cognitive or behavioural systems will always be problematic unless nondrug interventions that produce similar behavioural changes are also considered chronobiotic."

Yvan Touitou state that:

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“When treating sleep disorders of the circadian kind, special care must be given to distinguish compounds with chronobiotic properties from those with hypnotic effects. Whereas a chronobiotic may induce sleep by shifting the sleep–wake cycle so that sleep onset occurs earlier, a hypnotic will simply induce sleep without affecting the circadian mechanism.”

These compounds are active at the opioid like receptor which may mean that they are causing a simple hypnotic effect. In addition applicant has submitted evidence that the compounds are also active the mu opioid receptor. Mu receptor ligands are known to be hypnotics, and this information could explain a hypnotic effect as seen in the animal model. The animal model provided (Example 5) cannot distinguish between a hypnotic effect and an effect on the circadian mechanism. Toutitou explains that circadian rhythm sleep disorders do not respond appropriately to treatments - like hypnotics on pg. 295, line 1

“subgroups: A -- intrinsic sleep disorders, B-- extrinsic sleep disorders and C-- circadian rhythm sleep disorders.....in subgroup C, sleep mechanisms are functionally unaltered but the timing of the sleep-wake cycle is mismatched with the individual's circadian system or with the environmental or social appropriateness of time for sleep. This is why problems associated with subgroup C do not respond appropriately to treatments - like hypnotics, relaxation techniques, etc. - which are designed to deal with disorders of the sleep system itself. Sub-class C (circadian rhythm sleep disorders) is itself classified into seven subgroups: time zone change syndrome ("jet lag"), shift work sleep disorder, irregular sleep-wake pattern, delayed sleep-phase syndrome (DSPS), advanced sleep-phase syndrome (ASPS), non-24-hour sleep-wake disorders and "other" circadian rhythm sleep disorders. Not all these subgroups require the same action to compensate the altered sleep rhythm (Fig. 2). Jet lag and shift work syndromes need acceleration or prevention of the re-entrainment of the sleep-wake rhythm by phase-shifting, whereas DSPS and ASPS are permanent situations involving an altered phase relationship between sleep-wake and light-dark cycles and thus impaired entrainment processes. Non- 24-hour sleep-wake disorders are observed in, for example, blind persons, who require the entrainment of their free-running circadian sleep-wake cycle, while the irregular sleep-wake pattern involves a chaotic 24-h pattern of the sleep-wake rhythm and necessitates the reorganization of the circadian pacemaker by other Zeitgebers. “

Since these disorders stem from problems with the circadian mechanism and according to Toutiou the treatment of these disorders "necessitates the reorganization of the circadian pacemaker" and “these disorders do not respond appropriately to treatments - like hypnotics”, the conclusion reached by the examiner is justified. Furthermore, Toutitou states that “Not all these subgroups require the same action to compensate the altered sleep rhythm.”

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. ***Claims 21-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons outlined in the last office action.***

Conclusions

5. Claims 10-13, 28 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone number is (571)272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D.K.O.

/Janet L. Andres/

Supervisory Patent Examiner, Art Unit 1625